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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/523,114 | 08/02/2005 | Francois-Xavier Jacques Berthet | B45314 | 4557 |

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| EXAMINER | |
|---|---|
| ARCHIE, NINA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 01/17/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/523,114 | BERTHET ET AL. | |
| | Examiner | Art Unit | |
| | Nina A. Archie | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-71* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Group I: claims 1-19 and 45-47, and 51-55 drawn to an immunogenic composition.
2. Group II: claims 20-44 drawn to an isolated immunogenic composition comprising an outer membrane vesicle preparation.
3. Group III: claims 56-57 drawn to a method of treatment or prevention of Gram negative bacterial disease.
4. Group IV: claims 58-59, 61, 64, and 65 drawn to a use in the preparation of a medicament, a method of making the immunogenic composition, and a method of making the vaccine (Examiner interprets the use claim as a method of use in the preparation of a medicament).
5. Group V: claim 60 drawn to a genetically engineered Gram negative bacterial strain from which the outer membrane vesicles within the immunogenic composition can be derived.
6. Group VI: claims 62-63 drawn to a method of making the immunogenic composition comprising a step of isolating outer membrane vesicles from a Gram negative bacterial culture.
7. Group VII: claim 66 drawn to a method of preparing an immune globulin.
8. Group VIII: claims 67-68 drawn to an immune globulin preparation.
9. Group IX: claim 69 drawn to a pharmaceutical preparation comprising monoclonal antibodies.
10. Group X: claim 70 drawn to a method of treatment or prevention of Gram negative bacteria infection.

11. Group XI: claim 71 drawn to a use of the pharmaceutical preparation in the manufacture of a medicament for the treatment or prevention of Gram negative bacterial disease (Examiner interprets the use claim as a method of use in the pharmaceutical preparation in the manufacture of a medicament for the treatment or prevention of Gram negative bacterial disease).
12. Group XII: claims 48-50 drawn to an immunogenic composition comprising one or more polynucleotide(s) encoding a transferring binding protein or antigenic fragment thereof.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I is an immunogenic composition comprising an isolated transferring binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria. The technical feature of Group I is anticipated by Hermand et al WO 02/30458A1. Hermand et al teaches an immunogenic composition comprising an isolated transferring binding protein (Tbp) and an isolated Hsf like protein from the same or different Gram negative bacteria (see abstract and pgs. 1-5 and 13-16).

13. The technical feature of Group II is an isolated immunogenic composition comprising an outer membrane vesicle preparation.
14. Group III is a method of use of the technical feature of Group I, an immunogenic composition comprising an isolated transferring binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria.
15. Group IV is a method of use of the technical feature of Group I, an immunogenic composition comprising an isolated transferring binding protein (Tbp) or antigenic

fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria.

16. The technical feature Group V is a genetically engineered Gram negative bacterial strain from which the outer membrane vesicles within the immunogenic composition can be derived.
17. Group VI is a method of use of the technical feature of Group II, an isolated immunogenic composition comprising an outer membrane vesicle preparation.
18. Group VII is a method of use of the technical feature of Group VIII, an immune globulin preparation.
19. The technical feature of Group VIII is an immune globulin preparation.
20. The technical feature of Group IX is a pharmaceutical preparation comprising monoclonal antibodies.
21. Group X is a method of use of the technical feature of Group IX, a pharmaceutical preparation comprising monoclonal antibodies.
22. Group XI is a method of use of the technical feature of Group IX, a pharmaceutical preparation comprising monoclonal antibodies.
23. The technical feature Group XII is an immunogenic composition comprising one or more polynucleotide(s) encoding a transferring binding protein or antigenic fragment thereof.

Group II-XII lacks unity with Group I because they do not have the same technical feature.

The technical feature of Group I, an immunogenic composition comprising an isolated transferring binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria is known in the art. Group I lacks unity with Groups II-XI, because the technical feature of Group I is anticipated by the art and therefore not "special" within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art.

**Election of Species**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If the Applicant elects Group I or Group II, the Applicant is required to elect a combination of a single individual species from Species I, Species II, and Species III for Group I and II listed below.

Species I-Transferrin Binding Protein;

A) *Neisseria*;

B) *Moraxella catarrhalis*;

C) *Haemophilus Influenzae*;

Species II- Hsf like Protein;

A) *Neisseria*;

B) *Moraxella catarrhalis*;

C) *Haemophilus Influenzae*;

Species III- Polysaccharide;

A) *Neisseria;*

B) *Haemophilus influenzae B;*

C) *Streptococcus pneumoniae, Group A Streptococci, and Group B Streptococci;*

D) *Staphylococcus aureus and Staphylococcus epidermidis;*

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina Archie whose telephone number is 571-272-9938. The examiner can normally be reached on M-F 8:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie

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Patent Examiner
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MARK NAVARRO
PRIMARY EXAMINER